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| APPLICANT: Wolf, et al. | EXAMINER: Choi, Frank I. |
| SERIAL NO.: 09/524,716 | ART UNIT: 1616 |
| FILING DATE: March 14, 2000 | DOCKET NO.: 6671.US.01 |
| TITLE: CARBOHYDRATE SYSTEM AND A METHOD FOR PROVIDING NUTRITION TO A DIABETIC | I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Assistant Commissioner for Patents, Washington, D.C., 20231, on the date shown below. <i>Wendy Detweiler</i> 10-8-02 Wendy Detweiler Date |

Assistant Commissioner for Patents
Washington, D.C. 20231

REMARKS

I would like to thank the Examiner for scheduling a phone call to discuss the pending application on October 3, 2002. This amendment is based on our phone conversation and is in response to the Office Action mailed July 3, 2002. A request for a one-month extension of time accompanies this response. Claims 18, 19, 22 and 25 were allowed in the Office Action. Claims 6-22 and 25-27 remain active in this application. In this amendment, the Inventors have cancelled claims 6-10, 20, 21 and 26; and amended claims 11-17 and 27. The amendments have been made to better differentiate the claimed carbohydrate component of the diabetic nutritional from the prior art. Support for inclusion of nonabsorbent carbohydrate found on page 12, line 34 through page 13, lines 15.

Claims 6-17, 20, 21, 26 and 27 have been rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under U.S.C. 103(a) as obvious over Kaufman. Claims 6-10, 20, 21 and 26 have been cancelled rendering the above rejection related to these claims moot. As the Examiner has noted, Kaufman expressly discloses a food bar weighing 33 g containing uncooked corn starch, fructose, soy protein isolate, maltitol syrup, crisp rice, polydextrose, cocoa, non-fat milk, glycerine, canola oil, natural flavors, gum arabic and lecithin, providing 120 calories of which about 64% were from carbohydrate, 17% from protein and 19% from fat; containing 5

g protein, 2.5 g of fat and 22 g of carbohydrates of which 5 g were uncooked cornstarch, 17 g were more rapidly adsorbed carbohydrates, including 6 g of fructose, 3 g of maltitol and the remainder provided primarily by the polydextrose and peanuts (Example 3). The table below compares the percentage of total calories for the claimed nutritional of the instant invention and the Kaufman formulations.

| Macronutrient ranges (% of total kcal) | | |
|--|--------------------|---------------------|
| | Kaufman Ranges | Claimed Formulation |
| Total carbohydrate (CHO) | 50 - 75% | 25 - 55% |
| fructose | 12 - 88% total CHO | 5 - 50% total CHO |
| slowly adsorbed CHO | 20 - 88% total CHO | 0 |
| Protein | 10 - 25% | 10 - 35% |
| Fat | 10 - 25% | 25 - 37% |

The Examiner will note that the Kaufman formulations are able to teach away from the commercially available diabetic nutritionals described in the background of the specification, which contain higher fat and lower carbohydrate, and the claimed formulation of the instant invention, as Kaufman provides less fat and more carbohydrate in a serving. The Kaufman formulation is able to effectively reduce the incidence of blood glucose fluctuations because the formulas contain the slowly adsorbed uncooked starch. The claimed nutritional of the instant invention does not require the slowly adsorbed uncooked starch. The Inventors accomplish the same effect and distinguish their formula from Kaufman through the use of fructose and readily digested glucose polymers. Digestible glucose polymers are defined on page 7, lines 4-5 as rapidly digested. Further, the claimed nutritional of the instant formula requires nonabsorbant carbohydrates. Kaufman is silent to the use of nonabsorbant carbohydrates in a diabetic nutritional. One knowledgeable in the art would not substitute a rapidly adsorbed carbohydrate mixture into the Kaufman nutritional and expect to see the positive effects on blood glucose because Kaufman teaches that a combination of rapidly and slowly absorbed carbohydrate sources are required to obtain that result. Inventors request that the Examiner remove the rejection for claims 11-17 and 27.

Claims 6-17, 20, 21, 26 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al in view of Kaufman. Claims 6-10, 20, 21 and 26 have been cancelled rendering the above rejection related to these claims moot. As the Examiner has noted, Paul teaches a carbohydrate source comprising about 5-45% fructose and about 55-95% glucose polymers, which is assimilated immediately upon ingestion. Rapid delivery of nutrients to metabolically stressed persons is key to their nutritional support. Paul describes in the background the importance of the availability of appropriate amounts of nutrients (blend of carbohydrates, hydrolyzed protein and minerals) to supplant those that are utilized in a physiologically stressed patient (page 4, last paragraph). However, rapid emptying of the stomach and rapid absorption of nutrients is counter to the goal of the claimed diabetic formulas of the instant invention where a prolonged release of nutrients into the GI track and delayed metabolism of carbohydrates is key to help to delay or blunt the glycemic response. As seen in Figures 2 and 4 of the instant application, addition of fructose to a simple sugar or a glucose polymer, which Paul describes as being rapidly absorbed carbohydrates, blunts the postprandial response. This action would not have been expected based on the teachings of Paul.

As described above Kaufman teaches that the combination of fructose and slowly metabolized complex carbohydrates, such as uncooked cornstarch, helps to stabilize glucose levels. Based on this teaching, one knowledgeable in the art would not take the rapidly absorbed carbohydrate system of Paul and incorporate it into the diabetic formulation of Kaufman and expect to see the stabilized glucose levels because the Paul carbohydrate mixture does not include the slowly metabolized carbohydrate.

The amended claims require a carbohydrate mixture that consists of two rapidly absorbed carbohydrates, fructose and glucose polymer, and nonabsorbant carbohydrates. The nonabsorbant carbohydrate are described on page 8, line 5-10 of the specification. Additionally, neither of the references speak to the use of nonabsorbant carbohydrates in a diabetic formulation. Inventors request that the Examiner remove the rejection for claims 11-17 and 27.

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Respectfully submitted,

A handwritten signature in cursive script, appearing to read "N. Parlet", written over a horizontal line.

by Nickki L. Parlet
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REDLINED VERSION OF THE CLAIMS AMENDED HEREIN

IN THE CLAIMS:

11. (twice amended) A method for providing nutrition to an individual with diabetes comprising enterally administering a nutritional product comprising:
- a) [a] total carbohydrate [mixture comprising] from about 25% to about 55% of the total calories of the product, said carbohydrate [mixture comprising] consists of:
- i) a source of fructose from about 5 wt/wt% to about 50 wt/wt% of the total carbohydrate [mixture],
 - ii) at least one digestible glucose polymer source from about 50 wt/wt% to about 95 wt/wt% of the total carbohydrate [mixture],
 - iii) less than about 20 wt/wt% of the total carbohydrate [system as] is nonabsorbent carbohydrates,
- b) a source of fat [comprising] from about 25 to about 37% of the total calories of the product; and
- c) a source of protein [comprising] from about 10% to about 35% of the total calories of the product.
12. (amended) The [nutritional product] method according to claim 11 wherein said total carbohydrate [system] further comprises less than about 17 wt/wt% of the total carbohydrate [system] as dietary fiber selected from the group consisting of soluble fiber, insoluble fiber, fermentable fiber, non-fermentable fiber and mixtures thereof.
13. (amended) The [nutritional product] method according to claim 11 wherein said total carbohydrate [system] further comprises less than about 20 wt/wt% of the total carbohydrate [system] as indigestible oligosaccharides.

14. (amended) The [nutritional product] method according to [of] claim 11 wherein the source of fat comprises from about 25% to about 30% of the total calories of the product.
15. (amended) The [nutritional product] method according to [of] claim 11 wherein the source of protein comprises from about 15% to about 25% of the total calories of the product.
16. (amended) The [nutritional product] method according to [of] claim 11 wherein the total carbohydrate [system] comprises from about 35% to about 55% of the total calories of the product.
17. (amended) The [nutritional product] method according to [of] claim 11 further including at least one additional nutrient selected from the group consisting of vitamin A, vitamin B₁, vitamin B₂, vitamin B₆, vitamin B₁₂, vitamin C, vitamin D, vitamin E, vitamin K, biotin, carnitine, taurine, folic acid, pantothenic acid, niacin, choline, calcium, phosphorus, magnesium, zinc, manganese, copper, sodium, potassium, chloride, iron, selenium, chromium and molybdenum.
27. (amended) A method for blunting the postprandial glycemic response comprising enterally administering [the] a nutritional product [according to claim 11] comprising:
- a) [a] total carbohydrate [mixture comprising] from about 25% to about 55% of the total calories of the product, said carbohydrate [mixture comprising] consists of:
- i) a source of fructose from about 5 wt/wt% to about 50 wt/wt% of the total carbohydrate [mixture],
 - ii) at least one digestible glucose polymer source from about 50 wt/wt% to about 95 wt/wt% of the total carbohydrate [mixture],

- iii) less than about 20 wt/wt% of the total carbohydrate [system as] is nonabsorbent carbohydrates,
- b) a source of fat [comprising] from about 25 to about 37% of the total calories of the product; and
- c) a source of protein [comprising] from about 10% to about 35% of the total calories of the product.